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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/010,212

Applicant(s)

LEE ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,9,16-19,21,23-33,35 and 37-46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5,9,16 and 25-29 is/are allowed.
- 6) ☒ Claim(s) 17-19,21,23,24,30-33,35 and 37-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 17-19, 21, 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. With regards to claims 17 and 23, these claims are unclear because they claim structure that is not possible because of the amendments made to the claims. For example claim 17 claims a mandrel that extends to the inner surface of the polymeric reinforcing member, and therefore this would conflict with claim 1, which claims the polymeric tubular reinforcing member has an inner most surface along the entire length of the tubular reinforcing member. Therefore, if the mandrel were on the inner surface this would conflict with claim 1. Appropriate correction is required.

### *Claim Rejections –*

### *35 USC § 102 or 35 USC § 103*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 30 – 33, and 37-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Estrada et al. (USPN 6193686).

Estrada et al. discloses a balloon (15) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (27) formed of a first polymeric (PEEK) material having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal portion of the proximal tubular member. (Figures 1 – 11, Column 5, lines 8-45, and entire reference).

The examiner read through the specification and found the chemical compounds that makeup the reinforcing member and the proximal tubular member of the prior art and then looked up there glass transition temperatures on the internet. The examiner found the temperatures on the following two websites:

[http://www.zeusinc.com/peek\\_resin.asp](http://www.zeusinc.com/peek_resin.asp) (for nylon) and  
[www.sigmaaldrich.com/img/assets/3900/Thermal\\_Transitions\\_of\\_Homopolymers](http://www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf)  
.pdf – (for PEEK).

After reviewing the websites it is inherent that the PEEK will have a higher glass transition temperature than nylon and thus forming the basis for the rejection on this patent application.

7. Claims 30 – 33, and 37-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Happ et al. (USPN 6575958).

Happ et al. discloses a balloon (22) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (130) formed of a first polymeric material (col. 5, lines 49-68) having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal portion of the proximal tubular member. (Figures 1 – 19, Column 4, line 65 – Column 5, line 4, and entire reference).

The examiner read through the specification and found the chemical compounds that makeup the reinforcing member and the proximal tubular member of the prior art and then looked up there glass transition temperatures on the internet and the temperatures on the following two websites:

[http://www.zeusinc.com/peek\\_resin.asp](http://www.zeusinc.com/peek_resin.asp) (for nylon) and

[www.sigmaaldrich.com/img/assets/3900/Thermal\\_Transitions\\_of\\_Homopolymers.pdf](http://www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf) – (for PEEK).

After reviewing the websites it is inherent that the PEEK (reinforcing member) will have a higher glass transition temperature than nylon (proximal tubular member) and thus forming the basis for the rejection on this application.

***Claim Rejections - 35 USC § 103***

8. Claims 30-33, 35, and 37-39, 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verbeek (USPN 5690613), and further in view of Rau et al. (USPN 6024722) and in view of Samuelson et al. (USPN 6,165,166).

Verbeek discloses a balloon (35) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member (50) with a mandrel (30), a distal shaft section comprising an outer tubular member (80), and an inner tubular member (70) and a reinforcing member (13,17) formed of a first polymeric material polymeric reinforcing member around or within the proximal portion of the inner tubular member or the distal portion of the proximal tubular member, wherein a second polymeric material is used to form the distal portion of the proximal tubular member, as well as having a mandrel within the inflation lumen. (Figures 1A, 1B, 1C, and entire reference), but the reference fails to disclose the polymeric reinforcing member is formed from a thermoset or thermoplastic polyimide, and wherein the second polymeric material is formed from a nylon or polyether block amide, polyurethane, and adhesive polymer and wherein the

first polymeric material has a higher glass transition temperature than the second polymeric material.

Rau et al. discloses the use of thermoplastics and thermoset polyimide in balloon catheters because of the high strength and flexibility. (Column 1, line 32-45, and entire reference)

Samuelson et al. discloses a catheter with different layers and each layer has a different glass transition temperature, and wherein the outer layer has the greatest glass transition temperature, as compared to the inner most layer, which has the lowest glass transition temperature. The invention discloses that varying the glass transition temperature provides many advantages. (Column 4, lines 7-37).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Verbeek with the teachings of Rau et al. and Samuelson et al. because Rau et al. discloses the advantage of using a thermoset polyimide in a catheter wall because of the high strength and flexibility and Samuelson et al. disclosed using different polymers with different glass transition temperatures.

***Allowable Subject Matter***

9. Claim 1-5, 9, 16, 25-29 are in condition for allowance.

***Response to Arguments***

10. Applicant's amendments and arguments with respect to claim 1 has been considered and are persuasive.

11. With regards to claims 30-33, 35, 37-46. The examiner has not seen the limitation of the polymeric reinforcing member having the innermost surface that consists of the inflation lumen and only the inflation lumen. It is unclear to the examiner what the applicant is arguing with regards to these claims. The examiner has read through the remarks section several time and is still unclear as to the new limitations that were added that overcome the prior art, as well as the elements in the claims that overcome the prior art. Further clarification is needed with regards to these claims.

12. As to the 103 Rejection that involves Verbeek, Rau, and Samuelson, the examiner has followed the guidelines to establish a prima facie of obviousness (MPEP 2143.03). First there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings, second there must be a reasonable expectation of success. Finally the prior art reference must teach or suggest all of the claimed limitations.

13. The examiner meets these criteria's; by first pointing out what is lacking in the base reference, and then pointing out the location in the prior art reference the motivation to modify the base reference. Verbeek does not disclose the use of thermoset polyimides, which is taught by Rau. Rau also gives advantages to use these polyimides in catheters. Next Samuelson, discloses the use of layers, as well as wherein the layers will have different glass transition temperature. Samuelson further discloses benefits of using the elements as described in his invention. Therefore, once



all of these elements are combined, they formed the claimed invention in this application, and thus reason for the prima facie obviousness rejection.

### ***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto  
Art Unit 3763  
November 29, 2004



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